IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Edward J. Cheal et al. Art Unit: 3738

Serial No.: 10/605,322 Examiner: Stewart, Alvin

Filed: September 22, 2003 Confirmation No.: 2321

For: Joint Prosthesis and Components Atty. Docket: APK-001.02

Thereof

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/SCOTT F. KAMHOLZ/ Scott E. Kamholz

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

RESPONSE

Sir:

This Amendment is filed in response to the non-final Office Action mailed August 23, 2005. The Commissioner is authorized to charge any required fee to Deposit Account No. 06-1448, reference APK-001.02. Applicants claim entitlement to small entity status.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 1, 2, 5, 9, and 13-16 were rejected under 35 U.S.C. § 103(a) as reciting subject matter unpatentable over U.S. Pat. No. 5,002,578 to Luman in view of U.S. Pat. No. 4,212,087 to Mortensen. Claims 3, 4, 17, and 18 were rejected as reciting subject matter unpatentable over Luman in view of Mortensen and further in view of U.S. Pat. No.

5,653,764 to Murphy. Claim 6 was rejected as reciting subject matter unpatentable over Luman in view of Mortensen and further in view of U.S. Pat. No. 5,080,674 to Jacobs et al. Claims 7, 8, 19, and 20-25 were rejected as reciting subject matter unpatentable over Luman in view of Mortensen and further in view of U.S. Pat. No. 5,653,765 to McTighe et al.

In response, Applicants ask the Examiner to reconsider and withdraw these rejections because there is no suggestion in the cited references to combine Luman and Mortensen to reach the claimed subject matter.

In rejecting claims 1, 2, 5, 9, and 13-16, the Examiner stated (with emphasis added):

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substantially first cylinder [sic] of the Luman reference with the cylindrical press-fit connection of the Mortensen reference in order to permanently engage and fix the spigot to the bore of the stem member.

The italicized language appears to be the Examiner's statement of the motivation to combine Luman and Mortensen. But this statement merely points out a beneficial outcome that the Applicants first recognized could be obtained by combining features arguably found in those references. It does not show how the cited references themselves suggest that features selected from them should be combined in the manner that Applicants later taught. As discussed extensively in MPEP § 2143.01, "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." The suggestion to combine must be substantiated by reliance on objective evidence and specific factual findings. In re Lee,

277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002). The Examiner has pointed to no objective evidence or made any factual findings to establish that the cited references or the general knowledge suggest the desirability of combining Luman and Mortensen to reach the claimed subject matter. For this reason, the Examiner has not established a *prima facie* case of obviousness.

Moreover, the references themselves evidence the unobviousness of the claimed subject matter. When Luman filed his patent application in 1990, Mortensen's cylindrical press-fit had been known in the art for almost ten years. Despite this, Luman designed his modular prosthesis so that the stem and neck contact one another with a press-fit that is tapered, not cylindrical, and, as was explained in the Amendment filed September 27, 2004, must necessarily have suffered the low-tolerance drawback that tapered press fits exhibit. Indeed, Luman is forced to use a bolt 16 to secure the stem and neck together (col. 6, lines 32-35) presumably because of the tapered press-fit's lack of reliability. If using Mortensen's press-fit instead had been obvious, Luman would have done so and avoided the drawback that his arrangement exhibits.

Furthermore, Luman describes a complete, self-contained modular prosthesis that already provides a solution to the problem of securing the neck and stem portions: the bolt 16. It already achieves the beneficial result the Examiner identified, so one of ordinary skill in the art would have no reason to look to Mortensen to provide this result. To the contrary, the Examiner has used Applicants' own suggestion to secure the neck and stem with a cylindrical press-fit, discussed in paragraph [0024] of the specification, as a blueprint for combining Luman and Mortensen. This is impermissible hindsight. The

motivation must come from the prior art itself or the general knowledge, not from the

Applicant. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For these reasons, Luman and Mortensen cannot be combined to reach the subject

matter recited in claim 1 or in any claims dependent on claim 1. Luman and Mortensen $\,$

cannot be combined to reach the subject matter of claim 13 or its dependent claims for

similar reasons. None of the other references cited the claim rejections provides the

motivation that Luman and Mortensen lack.

Respectfully submitted, FOLEY HOAG LLP

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